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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632.949	07/31/2003	Masahiro Ishima	03461C/HG	5027

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EXAMINER	
BOESEN, AGNIESZKA	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,949	ISHIMA ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *17 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *5,7,9,11 and 17-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,8,10 and 12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *See Office Action*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received May 17, 2006.

Election/Restrictions

Applicant's election with traverse of group I, claims 1-4, 6, 8, 10, 12, 14 and 15 is acknowledged. Applicant argues that the peptide structures (IV) and (V) are structurally analogous to peptide structure (I). Applicant's argument has been fully considered and is persuasive. Structure (IV) that is claim 13, and structure (V) that is claim 16 are rejoined.

Claims 1-4, 6, 8, 10, and 12-16 are examined on the merits.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The Information Disclosure Statement received May 16, 2005, November 11, 2005, and July 31, 2003 have been considered and the copies are attached to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, and 4 and those dependent on claims 1, 2, and 4 are indefinite for reciting "glutamine-derived" because the exact meaning of the phrase is not clear or defined. The term "glutamine-derived" is not one, which has a universally accepted meaning in the art nor is it one which has been adequately defined in the specification. The primary deficiency in the use of this phrase is the absence of an ascertainable meaning for said phrase. Since it is unclear what are the specific derivatives of the glutamine, there is no way for a person of skill in the art to ascribe a discrete and identifiable class of compounds to said phrase. Further, it is not clear whether the "glutamine-derived" amino acid residues are formed by attachment of a detectable marker, therapeutic molecule, some other molecule or altering the amino acid sequence, for example. In addition, since the term "derived" does not appear to be clearly defined in the specification, and the term can encompass amino acid with attached chemical molecules. In absence of a single defined art recognized meaning for the phrase and lacking a definition of the term in the specification, one of skill in the art could not determine the metes and bounds of the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 6, 8, 10-12, 14, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to peptide or salt thereof, said peptide having, as constitutive amino acids, 4 glutamine-derived amino acid residues, 1 glutamic acid residue, 1 serine residue and 5 leucine residues, and having a 3-hydroxydecanoyl group that is bonded, via an amide linkage, to the N-terminal leucine residue thereof, the peptide is a depsipeptide having a cyclic structure. The claims are also drawn to a lower-alkylated derivative peptide of structure (I). The claims read on a genus of peptides that encompasses all peptides that comprise all recited components, such as amino acid and the functional groups. The recitation of the components of the peptide does not define the particular peptide structure. It is unknown how are the components arranged within the contemplated structures. Depending on the arrangement of the particular amino acids and functional groups, the peptide may lose the claimed antiviral activity or it may even acquire a different property. The instant specification provides insufficient description of all peptides that could be synthesized using the recited components of the peptide. The specification does not provide sufficient description or examples of the claimed derivatives of peptide structure (I). The

applicant has not shown that peptides, which have been derived from peptides of structure (I) are capable of exerting an antiviral activity as claimed.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factors present in the claims are the amino acids and functional groups that can be comprised in the peptide. There is absence of particular defined structure and with the particular positions of the amino acids and the functional groups in the peptide. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of peptides, and therefore conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement about which amino acids and functional groups are encompassed in the peptide. The

particular peptides are required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Thus there is insufficient written description support to demonstrate possession of complete genus comprising peptides that encompass components recited in the claims and the derivatives of the structure (I).

Claims 1, 2, 4, 6, 8, 10-12, 14, and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the structure (I), (IV), and (V), does not reasonably provide enablement for all structures that encompass the amino acids and the functional groups recited in the claims. The specification does not provide enablement for all lower alkylated derivatives of structure (I). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are

weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

The claims are broader in scope than the enabling disclosure. The specification discloses several peptide structures but the claims encompass a large genus of peptides and their derivatives.

2) Nature of the invention

The nature of the invention is directed to a peptide derived from a strain of *Pseudomonas.*

3) Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators conducting scientific research and development in this particular technological area possess an M.D. and/or a Ph.D. in a scientific discipline such as virology, immunology, organic synthetic chemistry, medicinal chemistry, biochemistry, pharmacology, biology or the like.

4) State of, or the amount of knowledge in, the prior art

The art teaches peptides derived from Pseudomonas species that have antiviral activity Nielsen et al (cited in the IDS).

5) Level or degree of predictability, or a lack thereof, in the art

Not all peptides that comprise the components recited in the current claims and not all lower-alkylated derivatives of peptide structure (I) will possess antiviral activity as instantly claimed. Thus, all peptides that comprise the recited amino acids and the functional groups or peptides that are derivatives of peptide structure (I) will not have antiviral activity.

6) Amount of guidance or direction provided by the inventor

Applicant was required to provide in the specification additional guidance and direction with respect to what are the specific structures that can comprise the amino acids and the functional groups recited in the claims as well as the derivatives of structure (I) and how effective are those peptides as antiviral agents.

7) Presence or absence of working examples

The specification fails to provide scientific data and working embodiments with respect to using peptides encompassed in the claimed genus as antiviral agents.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to reasonably and accurately determine whether all peptides comprising the amino acids and the functional groups recited in the claims would have been able to exert an antiviral activity. In conclusion, it is readily apparent from the aforementioned disclosure, in conjunction with a corresponding lack of scientific data and working embodiments regarding the claimed genus of peptides, that one of ordinary skill in the art would therefore be required to conduct an undue amount of experimentation to reasonably and accurately extrapolate whether said peptides have been able to act as antiviral agents.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3, 13, and 16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims, as written, do not sufficiently distinguish over peptides that exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. The claimed peptide which is derived from *Pseudomonas* species, occurs naturally. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor. See MPEP 2105.

Amendment of claims 3, 13, and 16 to recite "isolated peptide" would overcome this rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.
Examiner

7|20|06

Stacy B. Cha 7/20/06

STACY B. CHEN
PRIMARY EXAMINER